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Award Number: W81XWH-08-2-0047

TITLE: Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women

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REPORT DATE: August 2013

TYPE OF REPORT: ☐ Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

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REPORT DOCUMENTATION PAGE			<i>Form Approved</i> <i>OMB No. 0704-0188</i>	
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1. REPORT DATE (DD-MM-YYYY) Cwi wuv/4235		2. REPORT TYPE Tgxkugf "Annual		3. DATES COVERED (From - To) 1 April 2012"-31 July 2013
4. TITLE AND SUBTITLE Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women			5a. CONTRACT NUMBER	
			5b. GRANT NUMBER W81XWH-08-2-0047	
			5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Erica Yuen, PhD Ronald Acierno, PhD Wendy Muzzy, MS Go ckn'celgtpqB o wueqf w			5d. PROJECT NUMBER	
			5e. TASK NUMBER	
			5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Charleston Research Institute 176-A Ashley Ave. Charleston, SC 29403			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) US Army Medical Research Fort Detrick, Maryland 1702-5012			10. SPONSOR/MONITOR'S ACRONYM(S)	
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited				
13. SUPPLEMENTARY NOTES				
14. ABSTRACT This report describes key research accomplishments for Innovative Service Delivery for Secondary Prevention of PTSD between 4/1/12 and 7/31/13. This report focuses on the primary objectives for our fifth year including: a) recruitment and enrollment, b) the development and implementation of an efficient, sustainable, study-referral infrastructure, and c) presentation of the project at national conferences and submission and preparation of manuscripts..				
15. SUBJECT TERMS PTSD, OIF/OEF, Telemedicine, Behavioral Activation, Therapeutic Exposure, DOD/VHA research collaborations				
16. SECURITY CLASSIFICATION OF: U			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES "*****"17
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U		19a. NAME OF RESPONSIBLE PERSON USAMRMC
				19b. TELEPHONE NUMBER (include area code)

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INTRODUCTION:

The current project has two primary objectives: 1) evaluate the effectiveness of an intervention to prevent the functional impairment associated with PTSD symptoms in post-deployed OIF/OEF service men and women, and 2) determine whether or not this program delivered via telepsychology will be as effective as in-person treatment. Behavioral Activation and Therapeutic Exposure (BA-TE) is an eight-session, manualized treatment program. Using a between-groups, repeated measures design, study participants are randomized to one of two treatment conditions: BA-TE delivered via telepsychology (BA-TE-T), or BA-TE delivered in-person (BA-TE-IP). Participants will be assessed across primary and secondary outcome variables at five time points (pre-treatment, mid-treatment, post-treatment, and 3- and 12-month follow up).

BODY:

The major tasks of the S.O.W. include (1) **recruit** 248 active duty or veteran participants with PTSD or Sub-Threshold PTSD and randomly **assign** to either in person or televideo based treatment for PTSD; (2) collect measures of PTSD and other psychopathology, attendance, patient satisfaction and cost at pre-treatment, post-treatment, and follow-up. Note that our S.O.W. has been amended and approved to address the more prevalent problem of chronic PTSD by including up to 33% of Vietnam Veterans, in addition to OIE/OEF and Persian Gulf Veterans.

Report: 5 Year Point Data Analysis

Between 04/01/2012 and 07/31/2013, 587 participants were screened and 70 were enrolled, bringing our total enrollment to date since the initiation of study procedures on 10/08/2008 to 257. Note, enrolled participants are not considered to have been actually recruited until they attend the first treatment session. Additionally, 44 participants completed post-treatment assessment (132 total), 43 completed three-month follow-up (113 total), and 45 completed 12-month follow-up (90 total).

Participants were predominantly male (93%), White (49%) followed by Black (48%) and then Hispanic/Other (3%), and had a mean age of 44.4 years ($SD = 14.7$). Theatre was predominantly OIF/OEF (55%), followed by Vietnam (24%) and then Persian Gulf (21%). All participants endorsed symptoms consistent with either PTSD or subthreshold PTSD on the CAPs.

Clinical outcomes: Baseline to one-week post treatment (recent data update 12/1/13)

To evaluate the overall efficacy of BA-TE, we ran analyses on the PTSD Checklist-Military Version (PCL-M) and Beck Depression Inventory, Second Edition (BDI-II) for the entire sample collected as of 12/1/13. These analyses revealed significant within subject pre- to post-treatment reductions on the primary symptom measures. Consistent with hypotheses, analyses revealed significant reductions in PTSD and MDD symptoms over time, but no significant time by condition interactions. Considering the PCL for PTSD symptoms, within subjects reductions pre-treatment to post-treatment were significant ($F_{1,218} = 118.69$, $p < .001$); whereas between subjects comparisons at post treatment revealed no significant differences ($F_{1,218} = 0.03$, $p = .871$). Similarly, considering the BDI for Depression symptoms, within subjects reductions revealed pre-treatment to post treatment improvement ($F_{1,218} = 75.33$, $p < .001$), compared to no differences at post-treatment between telemedicine and in person treatment conditions ($F_{1,218} = 1.46$, $p = .228$).

Figure 1: PCL-M Score Pre-Post (N = 220)

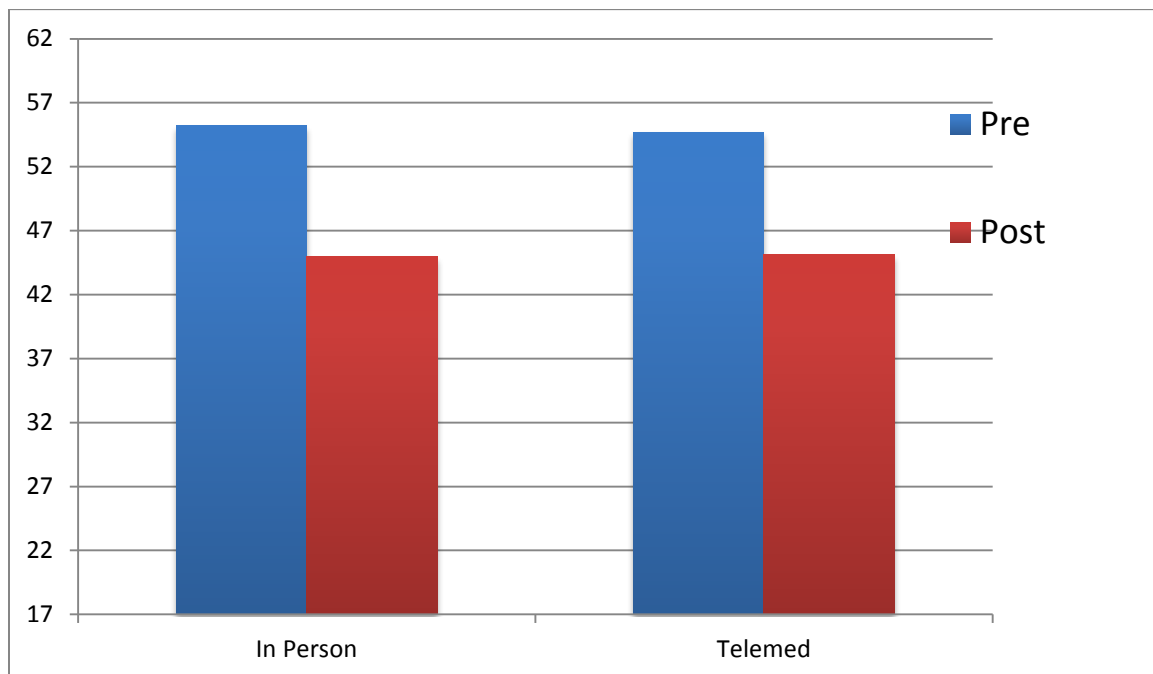
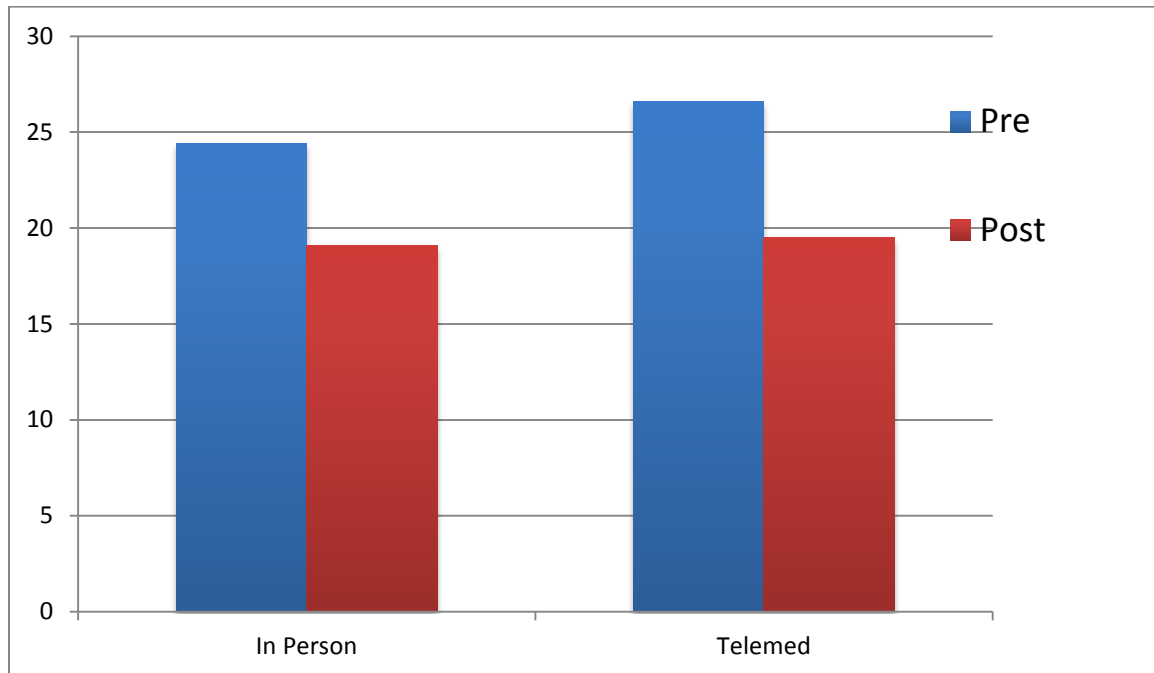


Figure 2: BDI Score Pre-Post (N = 220)



Trends At Follow Up (3 month and 12 month)

To date, 113 participants have completed the three-month follow-up assessment and 90 have completed 12 month assessment.

See figures below. In both figures, there is a significant effect for time (pre treatment vs. all other times), but no difference for treatment modality between groups at any time point.

Figure 3 presents PCL scores over time by condition N = 113 (3 mo), 90 (12 mo)

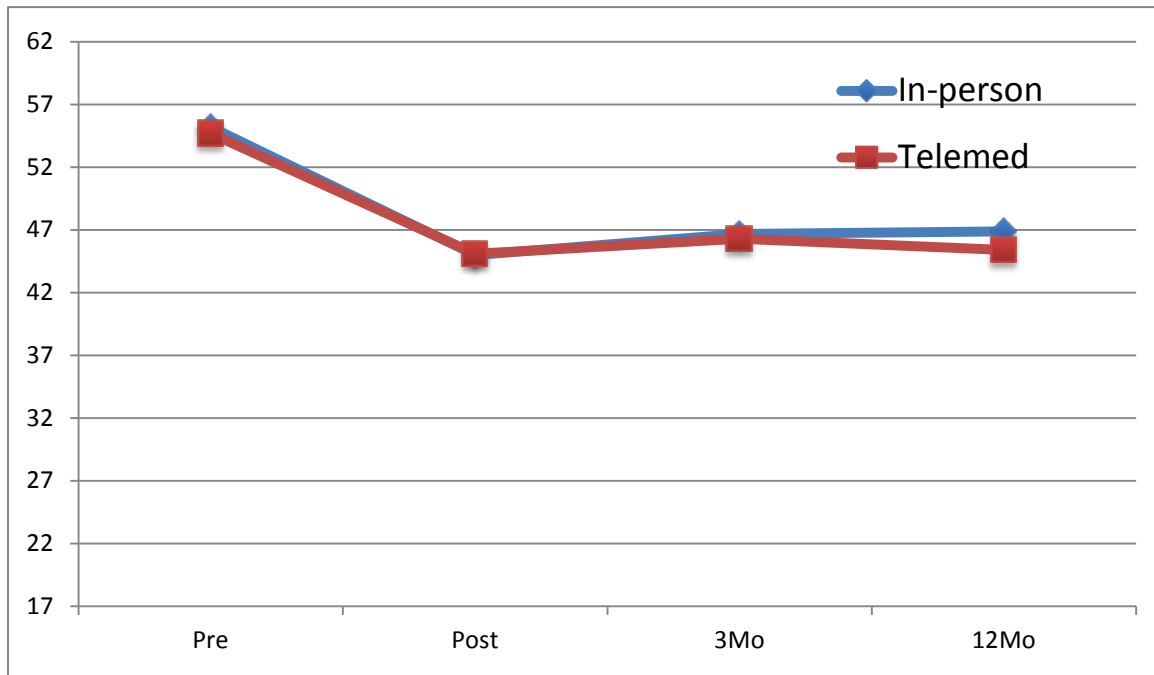
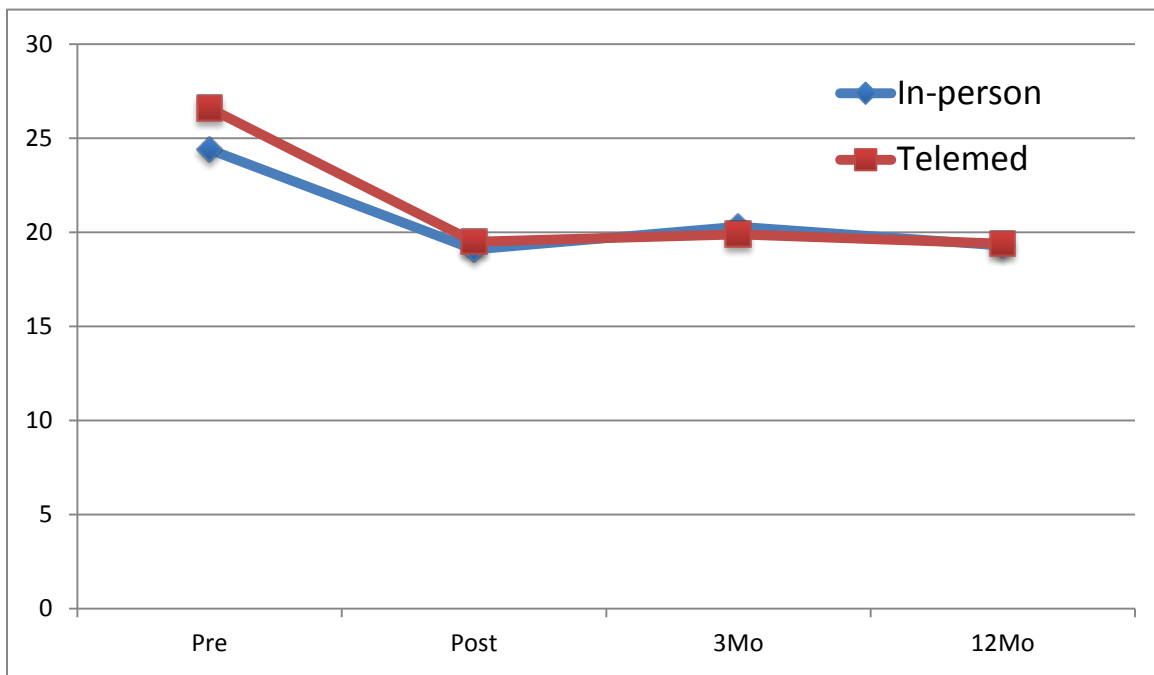


Figure 4 presents BDI scores over time by condition N = N = 113 (3 mo), 90 (12mo)



KEY RESEARCH ACCOMPLISHMENTS:

- 257 participants have been enrolled to date; 220 participants have completed post-treatment assessment; 113 participants have completed 3-month follow-up; and 90 participants have completed 12-month follow-up.
- Research staff has greatly increased efforts to advertise in the community this past year. Staff has advertised the study at local colleges, healthcare centers, counseling centers, community centers, churches, synagogues, community fairs, and PTSD support groups.
- Team representatives continue to maintain relationships with clinicians at our Goose Creek satellite clinic and primary care clinic annexes located in the Trident Hospital and the Charleston Naval Weapons Station.
- Research staff has continued with a postcard and phone call recruitment initiative; Veterans diagnosed with PTSD and receiving services at community-based outpatient clinics (e.g., Savannah, Myrtle Beach, Beaufort) are contacted via postcards/telephone to inform them of treatment opportunities through this study.
- Staff continues to meet weekly with Dr. Acierno (Principal Investigator) for clinical supervision. Other clinical training/supervisory experiences included attending weekly Grand Rounds seminars, assessment training seminars, and providing ongoing opportunities for clinical staff to shadow senior-level clinicians during therapy.
- We presented preliminary findings at several national and regional conferences (see next section).

REPORTABLE OUTCOMES:

- At this time, 13 manuscripts associated with this project have been submitted, published or are currently in press.
- 27 presentations associated with this project have been delivered at National/International/Regional conferences.
- 5 trainings/workshops have been delivered.
 - See Appendix Below.

CONCLUSION:

Recruitment has been steady, supported by the varied recruitment strategies implemented within the VA and surrounding community.

Preliminary results are consistent with current literature that suggests behavior therapies can be safely and effectively implemented via home-based telehealth technology and that telehealth service delivery yields reductions in symptomatology that are comparable to in-person service delivery. Participants who receive behavior therapy via telehealth report comparable treatment satisfaction, credibility, and service delivery perceptions to patients who receive exposure therapy via conventional in-person service delivery. Furthermore, preliminary results find that participants in both conditions appear to maintain their treatment gains at 3-month and 12-month follow-up.

Thus far, study findings are encouraging. On measures of both PTSD and MDD, within group improvements are evident, but no differences between telemedicine and in person conditions are evident. The latter findings are tempered, however, because power is still low relative to that suggested as necessary in non-inferiority designs. Nonetheless, lack of significant differences between modalities, with significant improvement within both modalities is worthy of note.

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None

APPENDICES:

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Price, M., Gros, D. F., Strachan, M., Ruggiero, K. J., & Acierno, R. (2012, November). The interactive effect of increased combat exposure and pre-deployment training on exposure therapy outcomes in PTSD for Operation Enduring Freedom/Operation Iraqi Freedom Veterans. In D. Grasso (Chair) Processes of Interpersonal Traumatic Stress. Paper presented at the 28th meeting of the International Society for Traumatic Stress Studies, Los Angeles, CA.

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Acierno, R. (2012, March). UPDATE: Secondary prevention of PTSD in at risk OIF-OEF service men and women: BA-TE via HOME based telemedicine. Paper presented at the MOMRP/CDMRP PTSD IPR Meeting, Bethesda, MD.

Price, M., Gros, D. F., Strachan, M., Ruggiero, K. J., Acierno, R. (2011, November). *The role of social support in the treatment of PTSD in OEF/OIF veterans*. Poster presented for the Disaster & Trauma Special Interest Group at the 45th annual meeting of the Association for Behavior and Cognitive Therapy, Toronto, Canada.

Price, M., Strachan, M., Gros, D., Ruggiero, K., Acierno, R. *Combat Experiences, Pre-deployment Training, and Outcome of Exposure Therapy for PTSD in Operation Enduring Freedom/Operation Iraqi Freedom Veterans*. (2011, November). Poster presented for the Disaster & Trauma Special Interest Group at the 45th annual meeting of for the Association for Behavior and Cognitive Therapy, Toronto, Canada.

Strachan, M., Price, M., Gros, D.F., Ruggiero, K.J., Acierno, R. (November, 2011). *Combat experiences, pre-deployment training, and outcome of exposure therapy for PTSD in OIF/OEF veterans*. Poster presentation at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, Toronto, ON.

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Acierno, R. (February 2011). *Secondary prevention of PTSD in at risk OIF-OEF service men and women: BA-TE via HOME based telemedicine*. Paper presented at the MOMRP/CDMRP PTSD IPR Meeting.

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- Yoder, M., Tuerk, P., Ruggiero, K., & Acierno, R. (2009, November). Prolonged exposure for Combat-Related PTSD: Differences in live vs. telehealth treatment delivery. Paper presented at the 25th Annual Meeting for the International Society for Traumatic Stress Studies, Atlanta, GA.
- Strachan, M. & Acierno, R. (2009, August). Innovative service delivery for the secondary prevention of PTSD in OIF/OEF service men and women. Paper presented at Military Health Research Forum (MHRF), Kansas City, KS.

Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women

PT073980/Award Number W81XWH-08-2-0047



PI: Ronald Acierno, Ph.D.

Org: Charleston Research Institute

Award Amount: \$1,445,214

Study/Product Aim(s)

- **Objective 1:** To evaluate the effectiveness of an intervention to prevent the functional impairment associated with PTSD symptoms in OIF/OEF, Persian Gulf, and Vietnam Veterans and service members.
- **Objective 2:** To determine whether or not this program delivered via telepsychology will be as effective as in-person treatment. Behavioral Activation and Therapeutic Exposure (BA-TE) is an eight-session, manualized treatment program.

Approach

A randomized between groups repeated measures non-inferiority design is being utilized. 250 active duty or Veteran participants with PTSD or Sub-Threshold PTSD are being recruited and randomly assigned to either in person or televideo-based treatment for PTSD. Data collection includes measures of PTSD and other psychopathology, attendance, patient satisfaction and cost at pre-treatment, post-treatment, and twelve month follow-up.



Accomplishments this Year:

- 587 participants were screened and 70 were enrolled, bringing our total enrollment to date since the initiation of study procedures on 10/08/2008 to 257.
- Additionally, 44 participants completed post-treatment assessment (132 total), 43 completed three-month follow-up (113 total), and 45 completed 12-month follow-up (90 total).
- 13 manuscripts associated with this project have been submitted, published or are currently in press.

Timeline and Cost

Activities	Year 1 4/08-4/09	Year 2 4/09-4/10	Year 3 4/10-4/11	Year 4 4/11-4/12	Year 5 4/12-4/13	Year 6+ 4/13-7/14
Initial approvals: IRB/VA/DoD	✓					
Recruitment / Treatment / Follow-up						
Data Analysis /Reports						
Dissemination						
Original Estimated Budget (Direct Costs)	\$322,201	\$ 293,776	\$297,983	\$305,732		

Goals/Milestones

Year 1 Goal – Institutional Human Subject Approvals Submitted. IRB, VA Research, DoD HRPO Approvals Obtained. Recruitment protocols and procedures established.

Year 2 Goals – Recruited and consented participants.

Year 3 Goals – Recruited and consented participants.

Year 4 Goals – Recruited and consented participants.

Year 5 Goals – Recruited and consented participants.

Year 6 Goals – Complete recruitment, analyze data, submit publications. Submit final report and presentations to DoD.

Comments/Challenges/Issues/Concerns

- 4-month no-cost extension (4/13-8/13)
- 6-month no-cost extension (8/13-2/14)
- 12-months funded extension (\$291,940; 8/13-7/14) would allow time and resources to meet recruitment goal, conduct follow-up, and complete data analyses and reports.

Budget Expenditure to Date

- Actual Expenditure: \$1,260,578 (as of 6/30/2013)

Updated: (8/16/2013)